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| EXAMINER |
|---|
| BLAKELY III, NELSON CLARENCE |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/506,875 | BEUME ET AL. | |
| | Examiner | Art Unit | |
| | NELSON C. BLAKELY III | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14,16-26,28-42 and 44-47* is/are pending in the application.

4a) Of the above claim(s) *10,12-14,16,22,24-26,31,33-40,44,46 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,17-21,23,28-30,32,41,42 and 45* is/are rejected.

7)☒ Claim(s) *2-9, 11, 18-21, 23, 29, 30, 41 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/02/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Application Status*

Claims 1-14, 16-26, 28-42 and 44-47 of the instant application are pending. Claims 10, 12-14, 16, 22, 24-26, 31, 33-40, 44, 46 and 47 are withdrawn pursuant to Applicant's Response, filed 01/21/2010. Accordingly, instant claims 1-9, 11, 17-21, 23, 28-30, 32, 41, 42 and 45 are presented for examination on their merits.

### *Election/Restrictions*

Applicant's election ***without traverse*** of Group I, claims 1-14, 17-26, 28-34, 39-42, 44 and 45, drawn to a pharmaceutical composition, a pharmaceutical product, and a kit, comprising a first active ingredient, which is selected from a PDE4 inhibitor, a PDE3/4 inhibitor and their pharmaceutically acceptable derivatives, and a second active ingredient, which is selected from a histamine receptor antagonist and its pharmaceutically acceptable derivatives, in the reply filed on 01/21/2010, is acknowledged.

It is acknowledged that Applicant elected wherein:

a) a single disclosed first active ingredient is roflumilast;

b) a single disclosed second active ingredient is cetirizine; and

c) a disclosed respiratory disease is allergic, seasonal or perennial rhinitis.

It is further acknowledged wherein claims 15, 27 and 43, drawn to a respiratory disease, are now canceled. Therefore, the election requirement to a disclosed respiratory disease is hereby ***withdrawn***.

Claims 10, 12-14, 16, 22, 24-26, 31, 33-40, 44, 46 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter, there being no allowable generic or linking claim. Election was made ***without traverse*** in the reply filed on 01/21/2010.

### *Priority*

Receipt is acknowledged of the certified copy of EP 02004987.0, filed 03/06/2002, submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Information Disclosure Statement*

The Information Disclosure Statement, filed 11/02/2004, is acknowledged.

### *Applicant's Amendment*

Applicant's Preliminary Amendment, filed 09/03/2004, wherein the specification and claims 2-14, 18-26, 29-34, 38-42 and 44-47 are amended, and claims 15, 27 and 43 are canceled, is acknowledged.

### *Claim Objections*

Claims 2-9, 11, 18-21, 23, 29, 30, 41 and 42 are objected to for the following informality:

With regard to claims 2-9, 11, 18-21, 23, 29, 30, 41 and 42, Applicant is encouraged to replace the term "A" with the term "The" at the beginning of the claims. The aforementioned claims are dependent claims.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 11, 18, 23, 29, 32, 41, 42 and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the first and second active ingredient, e.g., roflumilast and cetirizine, respectively, their pharmaceutically acceptable salts, N-oxide and salt of an N-oxide, does not reasonably provide enablement for their hydrate, solvate, hydrate of a salt, solvate of a salt, hydrate of an N-oxide, or solvate of an N-oxide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP § 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining

whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. The nature of the invention
2. The state of the prior art
3. The predictability or lack thereof in the art
4. The amount of direction or guidance present
5. The presence or absence of working examples
6. The breadth of the claims
7. The quantity of experimentation needed, and
8. The level of skill in the art

It is noted that all of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

*The State of the Prior Art and the Predictability or lack thereof in the art*

Active pharmaceutical ingredients are frequently delivered to the patient in the solid-state as part of an approved dosage form (e.g., tablets, capsules, etc.). Solids provide a convenient, compact, and generally stable format to store an active pharmaceutical ingredient or a drug product. Understanding and controlling the solid-state chemistry of active pharmaceutical ingredients, both as pure drug substances and in formulated products, is therefore an important aspect of the drug development process. Active pharmaceutical ingredients can exist in a variety of distinct solid forms, including polymorphs, solvates, hydrates, salts, co-crystals, and amorphous solids. Each form displays unique physicochemical properties that can profoundly influence the bioavailability, manufacturability purification, stability, and other performance characteristics of the drug. Hence, it is critical to understand the relationship between the particular solid form of a compound and its functional properties.

For ionizable compounds, preparation of salt forms using pharmaceutically acceptable acids and bases is a common strategy to improve bioavailability. However, the preparation of other solid forms such as polymorphs and solvates are not so common to be predictable. In order to obtain patent protection on these forms, some of which may have significantly different properties and relevance as development candidates, it is essential to prepare them, identify conditions for making them, and evaluate their properties as valuable new pharmaceutical materials. A large number of factors can influence crystal nucleation and growth during this process, including the composition of the crystallization medium and the processes used to generate super-saturation and promote crystallization (Morissette et al., Advanced Drug Delivery Reviews, Vol. 56, pages 275-300; 2004). Therefore, for these reasons, the state of the prior art is one of unpredictability.

As stated above, crystalline solids can exist in the form of polymorph, solvates or hydrates. "Phase transitions such as polymorph interconversion, desolvation of solvate, formation of hydrate, and conversion of crystalline to amorphous form may occur during various pharmaceutical processes, which may alter the dissolution rate and transport characteristics of the drug. Hence, it is desirable to choose the most suitable and stable form of the drug in the initial stages of drug development" (Vippagunta et al., Advanced Drug Delivery Reviews, Vol. 48, Abstract; 2001). In further discussing the predictability of the formation of solvates, Vippagunta et al. discloses that "predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid

compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compounds" (page 18, section 3.4).

*The Amount of Direction or Guidance Present and Presence or Absence of Working Examples*

The only direction or guidance present in the instant specification is for the first and second active ingredient, e.g., roflumilast and cetirizine, respectively, their pharmaceutically acceptable salts, N-oxide and salt of an N-oxide. See claim 2, for example. There are no data present in the specification for the preparation of hydrates or solvates of the compounds. The specification only discloses on page 21, lines 1-4, for example, that the compounds of the invention can exist in hydrated or solvated forms. The guidance in the specification is limited to the disclosure that certain compounds can exist in hydrate or solvate form; however, it is not discussed which specific compounds can exist in these forms. Finally, there are no working examples present in the disclosure that specifically indicate the preparation of hydrates or solvates.

*The Breadth of the Claims*

The instant breadth of the rejected claims is broader than the disclosure; specifically; the instant claims include any hydrates or solvates of the claimed compounds.

*The Quantity of Experimentation Needed and the Level of Skill in the Art*

While the level of skill in the pharmaceutical arts is high, it would require undue

experimentation for one of ordinary skill in the pertinent art to prepare *any* hydrate or solvate of the compounds. The science of crystallization has evolved such that, without mechanism of action guidance or data, such as working examples in the specification, the claims lack enablement.

Claims 1-6, 17, 18, 28, 29, 41, 42 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite the limitation, "pharmaceutically acceptable derivatives". Applicant has not described the claimed genus of "pharmaceutically acceptable derivatives" in a manner that would indicate Applicant was in possession of the full scope of this genus, or describe of what this genus is comprised. The instant specification, on page 21, lines 1-4, discloses that a pharmaceutically acceptable derivative of an active ingredient means a pharmaceutically acceptable salt or solvate (e.g., hydrate), a pharmaceutically acceptable solvate of such salt, a pharmaceutically acceptable N-oxide or a pharmaceutically acceptable salt or solvate of the latter. This exemplification is not a definition that allows the Examiner, or one of ordinary skill in the art, to ascertain that Applicant was in possession of the full scope of this genus.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert.

denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, "including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure…" *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although Eli Lily and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, Applicants have not described the genus of "pharmaceutically acceptable derivatives" in a manner that would allow one skilled in the art to immediately envisage the compounds contemplated for use. As such, the claims lack adequate written description for the claimed "pharmaceutically acceptable derivatives".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 17, 18, 28, 29, 41, 42 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "pharmaceutically acceptable derivatives" in claims 1-6, 17, 18, 28, 29, 41, 42 and 45, is a relative term which renders the claim indefinite. The term "pharmaceutically acceptable derivatives" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. One of ordinary skill in the art, at the time of the invention, would recognize that “pharmaceutically acceptable derivatives” would read on any compound having any widely varying groups that could possibly substitute the compounds. Any significant structural variation to a compound would be reasonably expected to alter, at least, its biological, physical and chemical properties. Thus, it is unclear of the metes and bounds of Applicant’s intent to the “pharmaceutically acceptable derivatives” encompassed herein.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 7-9, 11, 17, 19-21, 23, 41, 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gamache *et al*. (U.S. Patent No. 6,174,878B1).

With regard to instant claims 1, 5, 7-9, 11, 17, 19-21, 23, 41, 42 and 45, Gamache *et al*. disclose, in column 5, lines 17-19, compositions adapted for intranasal administration for the treatment of otic tissues, wherein the compositions may be in the form of nasal drops or an aerosol composition. In column 6, lines 1-38, Gamache *et al*. disclose wherein the compositions of the reference invention may contain one or more histamine $H_1$ receptor antagonists, or anti-histaminic agents (e.g., cetirizine, line 10),

which may be dosed concurrently or sequentially with anti-allergy agent containing compositions. In the instant excerpt, Gamache *et al*. further disclose wherein the compositions of the reference invention may also contain one or more anti-inflammatory agents, e.g., PDE IV inhibitors (roflumilast, line 38), which may be dosed concurrently or sequentially with anti-inflammatory agent containing compositions. See instant claims 1, 5, 7-9, 11, 17, 19-21, 23, 41, 42 and 45.

Therefore, a skilled artisan would have envisaged the instantly claimed pharmaceutical composition comprising an anti-inflammatory agent, e.g., roflumilast, and an anti-histamine, e.g., cetirizine, as disclosed by Gamache *et al*. One of ordinary skill in the art would have been motivated to combine the aforementioned active ingredients when seeking a pharmaceutical composition useful in treating a condition, e.g., allergic, seasonal or perennial rhinitis, arising from allergens, or an allergenic stimuli, and inflammation. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art suggests the claimed invention.

Accordingly, the instant invention, as claimed in claims 1, 5, 7-9, 11, 17, 19-21, 23, 41, 42 and 45, is *prima facie* obvious over the combination of the aforementioned teachings.

Claims 2-4, 6, 18, 28-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gamache *et al*. (U.S. Patent No. 6,174,878B1), as applied to claims

1, 5, 7-9, 11, 17, 19-21, 23, 41, 42 and 45 above, and further in view of Bratzler *et al.* (U.S. Patent Application Publication No. 2004/0067902A9).

With regard to instant claims 2-4, 6, 18, 28-30 and 32, the teachings of Gamache *et al.* are set forth *supra*.

Gamache *et al.* fail to disclose specifically wherein the first and/or second active ingredient is in the form of a pharmaceutically acceptable salt (instant claims 2, 18, 29), the pharmaceutical composition is a fixed oral combination (instant claim 3), said composition is a dry powder for use in a dry powder inhaler (instant claim 4), said composition is combined with a propellant to form a composition delivered using a metered dose inhaler (instant claim 6), or a kit comprising a preparation of a first and second active ingredient and instructions for simultaneous, sequential or separate administration to the patient in need thereof (instant claims 28, 30 and 32). However, Bratzler *et al.* disclose, in the Abstract, an invention involving the administration of an immunostimulatory nucleic acid in combination with an asthma/allergy medicament for the treatment of asthma and allergy in subjects, wherein the invention also relates to kits and compositions concerning the combination of drugs. In paragraph **[0036]**, Bratzler *et al.* disclose wherein the asthma/allergy medicament is cetirizine. Bratzler *et al.* disclose, in paragraphs **[0182]** and **[0183]**, wherein the asthma/allergy medicament is housed in at least one container, or kit, wherein the kit also has instructions for timing of administration of the asthma/allergy medicament, and would direct the subject having asthma/allergy or at risk of asthma/allergy to take the asthma/allergy medicament at the appropriate time. In the instant excerpt, specifically paragraph **[0183]**, Bratzler *et al.*

further disclose wherein the instructions in the kit direct the subject to take the immunostimulatory nucleic acid and the asthma/allergy medicament in amounts which would produce a synergistic immune response, and wherein the drugs may be administered simultaneously or separately as long as they are administered close enough in time to produce a synergistic response. See instant claims 28 and 30. Bratzler *et al*. disclose, in paragraph **[0187]**, wherein the asthma/allergy medicaments are preferably inhaled, ingested or administered by local routes, e.g., nasal drops, and wherein the inhaled medications are administered by metered dose inhalers and dry powder inhalers. See instant claims 4 and 6. In paragraphs **[0189]** and **[0193]**, Bratzler *et al*. disclose wherein the compounds may be administered orally or conveniently delivered in the form of an aerosol spray presentation from pressurized packs or a nebulizer with the use of a suitable propellant. See instant claims 3 and 6. Bratzler *et al*. disclose, in paragraph **[0201]**, wherein the compounds may be administered in the form of pharmaceutically acceptable salts. See instant claims 2, 18 and 29.

Therefore, a skilled artisan would have envisaged the instantly claimed pharmaceutical composition comprising an anti-inflammatory agent, e.g., roflumilast, and an anti-histamine, e.g., cetirizine, as disclosed by Gamache *et al*., in conventional forms of administration, e.g., a kit with instructions for use, a dry powder inhaler, a metered dose inhaler, as disclosed by Bratzler *et al*. One of ordinary skill in the art would have been motivated to combine the aforementioned active ingredients when seeking a pharmaceutical composition useful in treating a condition, e.g., allergic, seasonal or perennial rhinitis, arising from allergens, or an allergenic stimuli, and

inflammation via various conventional routes of administration, e.g., oral, inhalation and intranasal. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art suggests the claimed invention.

Accordingly, the instant invention, as claimed in claims 2-4, 6, 18, 28-30 and 32, is *prima facie* obvious over the combination of the aforementioned teachings.

## ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is (571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614
May 28, 2010

/N. C. B. III/
Examiner, Art Unit 1614